IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	**Master File No: 1:13-MD-2419-RWZ**

This document relates to:

***Agnew v. Insight Health Corp. et al.*, Case No. 1:14-cv-13505-RWZ;**
***Andrews v. Insight Health Corp. et al.*, Case No. 1:14-cv-13509-RWZ;**
***Artis v. Insight Health Corp*, Case No. 1:14-cv-12942-RWZ;**
***Austin et al. v. Insight Health Corp. et al.*, Case No. 1:14-cv-13504-RWZ;**
***Baker v. Image Guided Pain Management, P.C.*, Case No. 1:14-cv-12421-RWZ;**
***Bell et al. v. Insight Health Corp. et al.*, Case No. 1:14-cv-13511-RWZ;**
***Bender v. Insight Health Corp.*, Case No. 1:14-cv-12978-RWZ;**
***Bishop v. Insight Health Corp. et al.*, Case No. 1:14-cv-13510-RWZ;**
***Bradley v. Insight Health Corp.*, Case No. 1:14-cv-12919-RWZ;**
***Brown v. Insight Health Corp.*, Case No. 1:14-cv-12941-RWZ;**
***Brown v. Insight Health Corp.*, Case No. 1:14-cv-12938-RWZ;**
***Buchanan v. Insight Health Corp. et al.*, Case No. 1:14-cv-13507-RWZ;**
***Courtney v. Insight Health Corp.*, Case No. 1:14-cv-12931-RWZ;**
***Epperly v. Insight Health Corp.*, Case No. 1:14-cv-12905-RWZ;**
***Filson v. Insight Health Corp.*, Case No. 1:14-cv-12917-RWZ;**
***Foutz v. Insight Health Corp.*, Case No. 1:14-cv-12924-RWZ;**
***Gaskins v. Insight Health Corp. et al.*, Case No.[1]**
***Harris v. Insight Health Corp.*, Case No. 1:14-cv-12928-RWZ;**
***Holbrook v. Insight Health Corp.*, Case No. 1:14-cv-12930-RWZ;**
***Johnston v. Alaunus Pharmaceutical, LLC*, Case No. 1:14-cv-12937-RWZ;**
***Kalinoski v. Insight Health Corp.*, Case No. 1:14-cv-12916-RWZ;**
***McFarlane v. Insight Health Corp.*, Case No. 1:14-cv-12908-RWZ;**
***Miller v. Insight Health Corp., et al.*, Case No. 1:14-cv-13508-RWZ;**
***Neal v. Insight Health Corp. et al.*, Case No. 1:14-cv-13496-RWZ;**
***Shuck v. Insight Health Corp.*, Case No. 1:14-cv-12939-RWZ;**
***Smith (James) v. Insight Health Corp.*, Case No. 1:14-cv-12910-RWZ;**
***Smith (Randolph) v. Insight Health Corp.*, Case No. 1:14-cv-12929-RWZ;**
***Wertz v. Alaunus Pharmaceuticals, LLC*, Case No. 1:14-cv-12933-RWZ;**
***White v. Insight Health Corp.*, Case No. 1:14-cv-12940-RWZ;**
***Whitlow v. Insight Health Corp.*, Case No. 1:14-cv-12927-RWZ.**

[1] Transferred via electronic order on 8/28/14, but not yet assigned a case # in ECF.

Consolidated Memorandum in Support of Motion for Partial Judgment on the Pleadings by Defendants John Mathis, M.D., Robert O'Brien, M.D., and Image Guided Pain Management, PC

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CONTENTS

PRELIMINARY STATEMENT

Defendants John M. Mathis, M.D., and Robert F. O'Brien, M.D., are physicians who treated Plaintiffs and/or their decedents. They own, operate, and are employed by a professional corporation, Image Guided Pain Management, P.C. Plaintiffs' lawsuits against these three defendants assert what are, at bottom, medical-malpractice claims. They claim that Dr. Mathis and Dr. O'Brien injected them with contaminated steroids, causing serious injury. A claim by a patient against his doctor is a claim for medical malpractice. But rather than making straightforward malpractice claims, however, Plaintiffs' complaints assert a panoply of causes of action, including fraud, battery, negligence per se (based on violation of consumer rights and violations of drug regulations), and even U.C.C. claims for breach of warranty.

These legal theories have nothing to do with the alleged facts concerning Dr. Mathis and Dr. O'Brien. The fraud claims are impermissibly vague about who told what to whom—lumping the doctors together with Co-Defendant Insight Health Corp. and lacking the specificity that Rule 9(b) requires. The negligence per se claims fail because the Virginia Medical Malpractice Act alone establishes the standard of care for physicians in malpractice actions. Plaintiffs cannot plead around it with their novel negligence-per-se theories. As for the battery counts, these are just disguised lack-of-informed-consent claims. Finally, the U.C.C. claims do not apply because Drs. Mathis and O'Brien primarily sold medical services, not medical supplies.

Image Guided and Drs. Mathis and O'Brien bring the present motion under Rule 12(c) to prune these superfluous and inapposite claims. For the reasons stated below, this Court should dismiss all but the simple negligence claims against Dr. Mathis, Dr. O'Brien, and Image Guided.

STATEMENT OF ALLEGED FACTS[2]

Defendants John Mathis, M.D., and Robert O'Brien, M.D., are radiologists employed by Image Guided Pain Management, PC, a medical practice in Roanoke, Virginia (collectively, the "Image Guided Defendants"). Plaintiffs, or their decedents, were treated by Dr. Mathis and Dr. O'Brien in 2012 at Insight Imaging—Roanoke. In particular, Dr. Mathis and Dr. O'Brien performed image-guided injection of the steroid methylprednisolone acetate ("MPA").

The MPA that the Image Guided Defendants used was provided to them by Defendant Insight Health Corp. ("Insight"). Insight, in turn, obtained the MPA from the New England Compounding Pharmacy, Inc. ("NECC"), a compounding pharmacy in Massachusetts. Because NECC is a compounding pharmacy, the MPA that it produced was not regulated by the FDA.

In 2012, there were several well-publicized adverse events resulting from fungal contamination of medications prepared by NECC. The MPA that Insight purchased—and that the Image Guided Defendants used during the procedures at issue—was among the contaminated batches. Plaintiffs assert that, as a consequence, they (or their decedents) suffered serious injury.

Plaintiffs have sued the Image Guided Defendants for their alleged misconduct in the use of NECC-prepared MPA. Among other things, Plaintiffs allege that the Image Guided Defendants and Insight either concealed or misrepresented the source of the MPA that they used during the procedures. They allege that the Image Guided Defendants concealed from their patients the fact that the MPA used in the procedures was compounded MPA, not commercially available MPA. They allege that the Image Guided Defendants and Insight referred to "Depo-Medrol"—Pfizer's brand-name for its commercially available MPA product—in various pieces of their literature or when discussing the procedure with patients. And they allege that the Image

[2] Citations to the particular allegations in the individual complaints encompassed by the present Motion are attached as a separate document, **Exhibit 1**.

Guided Defendants' procedure notes, and Insight's invoices and insurance claims incorrectly reference commercially prepared MPA, rather than compounded MPA.

Based on these allegations—addressed more fully below—Plaintiffs assert claims for negligence per se, battery, fraud, constructive fraud, breach of the Virginia Consumer Protection Act, and breach of UCC warranties. All of these claims fail as a matter of law. As to the Image Guided Defendants, Plaintiffs have stated, at most, a claim for medical negligence.

ARGUMENT

I. Standard of Review[3]

Rule 12(c) motions are governed by the same standard as Rule 12(b)(6) motions. *Cavic v. Am.'s Servicing Co.*, 806 F. Supp. 2d 288, 290 (D. Mass. 2011) ("The standard for evaluating a Rule 12(c) motion for judgment on the pleadings is the same as the standard for deciding a Rule

[3] In an October 31, 2013 letter opinion—issued before these cases were removed and transferred to this Court—the Circuit Court of the City of Roanoke, Virginia, addressed some of the legal issues presented here. This was in the context of a "demurrer" filed by Defendants in *Wingate v. Insight*, No. CL12002547-00, a case that has since settled. To the extent that that that letter opinion carries any force in any of the cases now before this Court, this Court should vacate it and reconsider the issues independently. There are two reasons for this.

First, Virginia's demurrer standard is far less exacting than the federal *Twombly*/*Iqbal* standard for Rule 12(b)(6) and 12(c) motions. Whereas the *Twombly*/*Iqbal* test requires that the complaint state a claim that is plausible, *see infra*, Virginia's demurrer standard requires only that the claim be intelligible. *See, e.g.*, *Assurance Data, Inc. v. Malyevac*, 747 S.E.2d 804, 807-08 (Va. 2013) ("When a complaint contains sufficient allegations of material facts to inform a defendant of the nature and character of the claim, it is unnecessary for the pleader to descend into statements giving details of proof in order to withstand demurrer. [E]ven though a ... complaint may be imperfect, when it is drafted so that defendant cannot mistake the true nature of the claim, the trial court should overrule the demurrer.") (internal citations omitted) (brackets and ellipsis in original).

Where, as here, the governing legal standard differs between the state court where the action originated and the federal court to which the action has been removed, federal courts should reconsider the merits of the ruling: "A federal court has particularly good reason to reconsider a state court determination where federal standards differ from state law standards on an issue." Wright & Miller, 14C Fed. Prac. & Proc. § 3738 (4th ed.). *See also Nasso v. Seagal*, 263 F. Supp. 2d 596, 610 (E.D.N.Y. 2003) (reconsidering state-court ruling on motion to dismiss where state court standard differed from Rule 12(b)(6) standard); *Fairbank v. Wunderman Cato Johnson*, 212 F.3d 528, 531 (9th Cir. 2000) (holding that district court properly reconsidered summary judgment ruling where state standard differed from Rule 56 standard).

Second, the Roanoke Circuit Court's rulings vis-à-vis the Image Guided Defendants' demurrers were plainly erroneous. (The court also included a discussion of the Image Guided Defendants' pleas in bar, but later agreed that these were not properly before the court. No order ever was entered on them.) Its discussion is cursory in the extreme and largely hinges on the fact that the allegations in the plaintiff's complaint lumped the Image Guided Defendants' together with the Insight defendants without explaining who did what.

This Court can and should hear the present motion on the merits.

12(b)(6) motion to dismiss.") (citing *Remexcel Managerial Consultants, Inc. v. Arlequin*, 583 F.3d 45, 49 & n. 3 (1st Cir.2009)). For a complaint to state a claim under either standard, it must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although "detailed factual allegations" are not necessary, a plaintiff must include more than just "labels and conclusions." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "[A] formulaic recitation of the elements of a cause of action will not do." *Id.* The factual allegations must be sufficient to elevate the claim for relief "above the speculative level" and demonstrate the existence of a claim that is "plausible on its face." *Id.* at 555, 570.

A claim is "plausible on its face" only where "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by merely conclusory statements, do not suffice." *Id.* To be given credence, legal allegations must be supported by factual allegations. *Id.* at 679. Pleadings that "are no more than conclusions" are not plausible on their face and, under the Supreme Court's rulings in *Twombly* and *Iqbal*, should be dismissed. *Id.*

II. Plaintiffs' negligence per se claims fail because (1) the Virginia Drug Control Act does not establish a tort duty of care, (2) it does not establish the standard for evaluating whether a physician has complied with its duty of care, and (3) the alleged facts do not establish a statutory violation.

A. A party asserting a "negligence per se" claim must establish all of the elements of a traditional negligence cause of action.

In their various complaints, Plaintiffs assert claims for "negligence per se" against Image Guided, Dr. Mathis, and Dr. O'Brien, based on alleged violations of Virginia's Drug Control

Act.[4] The negligence per se doctrine enables a plaintiff to use a public-safety statute as the relevant standard of care in a negligence claim. *Steward v. Holland Family Properties, Inc.*, 726 S.E.2d 251, 254 (2012). The negligence per se doctrine does not, however, create a duty where none existed before. *Id.* ("[A] statute setting the standard of care does not create the duty of care."). It just supplies a statutory standard that can be used to evaluate whether the defendant breached an otherwise-existing duty of care. *Id.* Put another way, the doctrine simply provides a way for a plaintiff to prove one element—breach of a preexisting duty—in a negligence claim. It is not a free-standing cause of action.[5] More to the point, it does not relieve a plaintiff from the obligation to establish the other elements of a negligence claim. *Id.* ("All negligence causes of action are based on allegations that a person having a duty of care to another person violated that duty of care through actions that were the proximate cause of injury to the other person.").

Thus, a negligence per se claim will fail if the plaintiff cannot establish a common-law duty of care that the defendant allegedly breached. Likewise, a plaintiff cannot base a negligence claim on a statutory breach where that breach did not injure the plaintiff. Finally, the negligence per se doctrine is a common law doctrine that the Virginia General Assembly is free to override where it deems appropriate. Plaintiffs' arguments fall afoul of these principles.

B. Virginia's Medical Malpractice Act—not the common law or the Drug Control Act—defines the standard of care in actions against physicians.

Take, first, the question of whether the doctrine has been superseded by statute in the medical context. Virginia's Medical Malpractice Act ("Act"), Va. Code § 8.01-581.1 *et seq.* is a

[4] To assist the Court's analysis of the various cases, Defendants have attached as **Exhibit 2** a chart, arranged by count, identifying which Plaintiffs are asserting which causes of action. Attached as **Exhibit 3** is a similar chart, but arranged by case name. Finally, attached as **Exhibit 4** is another chart organizing the cases by law firm.

[5] The Plaintiffs in certain of the cases cite Virginia Code § 8.01-221, which states that a person harmed by a statutory violation may bring an action for such harm. But this statute merely preserves preexisting causes of action; it does not create any new ones. *Field v. GMAC LLC*, 660 F. Supp. 2d 679, 689 (E.D. Va. 2008) (citing *Vansant and Gusler, Inc. v. Washington*, 429 S.E.2d 31, 34 (Va. 1993)).

comprehensive statute addressing the prerequisites and procedures for malpractice actions against Virginia health care providers. Virginia Code § 8.01-581.1 defines "malpractice" as "any tort action . . . for personal injuries or wrongful death, based on health care or professional services rendered, or which should have been rendered, by a health care provider, to a patient." The Act governs the claims that Plaintiffs have asserted against Image Guided, Dr. Mathis, and Dr. O'Brien. Image Guided, Dr. Mathis, and Dr. O'Brien are "health care providers," as that term is defined under the Act.[6] The present case is a "tort action" for "personal injuries." And it is "based on health care or professional services rendered." So the terms of the Act apply.

Relevant here, the Act defines the standard of care to be used in medical malpractice actions brought against physicians. Va. Code § 8.01-581.20(A). It states that "in any action against a physician . . . or other health care provider to recover damages alleged to have been caused by medical malpractice where the acts or omissions so complained of are alleged to have occurred in this Commonwealth, *the standard of care by which the acts or omissions are to be judged* ***shall*** *be that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in this Commonwealth*." *Id.* (emphasis added).[7] The Act does *not* incorporate Virginia's Drug Control Act as defining, even in part, the standard of care for physicians in Virginia. *Id.*

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[6] See Code § 8.01-581.1 ("'Health care provider' means (i) a person, corporation, facility or institution licensed by this Commonwealth to provide health care or professional services as a physician . . . ; [and] (ii) a professional corporation, all of whose shareholders or members are so licensed . . . .").

[7] The Medical Malpractice Act also specifies how to establish whether or not a defendant physician has met the standard of care, stating that "the testimony of an expert witness, otherwise qualified, as to such standard of care, shall be admitted." Va. Code § 8.01-581.20(A). Unless the matter lies within the common experience of the jury, a medical-malpractice plaintiff needs expert testimony "to establish the appropriate standard of care, to establish a deviation from the standard, and to establish that such a deviation was the proximate cause of the claimed damages." *Raines v. Lutz*, 341 S.E.2d 194, 196 (Va. 1986). And an expert is qualified only "if he demonstrates expert knowledge of the standards of the defendant's specialty and of what conduct conforms or fails to conform to those standards and if he has had active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action." *Id.* Code § 8.01-581.20(A).

In the present case, Plaintiffs are attempting to use the common-law negligence-per-se doctrine to circumvent the standard of care that the Virginia General Assembly has established for medical-malpractice actions. That is improper. For this reason alone, this Court should reject all of Plaintiffs' negligence-per-se arguments.

C. Plaintiffs' negligence per se claims fail because there is no common-law tort duty of care vis-à-vis the handling of drugs.

Plaintiffs' negligence-per-se claims fail for the additional reason that the statutory obligations that the Image Guided Defendants allegedly violated do not correspond to any underlying tort duty of care. Where negligence per se applies, it merely establishes the standard of care for a preexisting duty; it does not create the duty of care in the first place. *Steward*, 726 S.E.2d at 254 (Va. 2012). Thus, "to proceed with a negligence per se action, a plaintiff must first establish a duty based in tort." *Id.* at 256.

In the present case, Plaintiffs' negligence per se claims are not based on the violation of any preexisting tort duty. The statute they rely on, the Virginia Drug Control Act, governs the handling, labeling, and sale of pharmaceuticals. Va. Code § 54.1-3400 *et seq*. Plaintiffs allege that the Image Guided Defendants violated this statute inasmuch as the MPA was prescribed incorrectly or was "misbranded" and "adulterated." But these claims do not allege the violation of any common-law-negligence duty of care owed by a physician to a patient. Indeed, it was precisely to fill gaps in the law that Congress and the states enacted their various drug-control acts. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009) (giving history of federal regulation of drugs). Because the alleged violations of the Drug Control Act do not correspond to any common-law duty of care, Plaintiffs cannot ground their negligence-per-se argument on them.

D. Plaintiffs' negligence per se claims fail because the Image Guided Defendants did not violate Virginia's Drug Control Act.

Finally, even assuming that Plaintiffs can bypass the Medical Malpractice Act's standard of care by using the negligence-per-se doctrine (and they cannot), even assuming that the alleged violations of the Drug Control Act correspond to a common-law duty of care (and they do not), and even assuming they plausibly caused their injuries (and they do not), Plaintiffs' negligence per se claims still fail because—under the facts alleged—the Image Guided Defendants did not violate the Virginia Drug Control Act. None of the cited sections apply to the Image Guided Defendants' alleged actions.[8]

Take, first, **Virginia Code § 54.1-3408.01**. This requires that a written prescription "contain the first and last name of the patient for whom the drug is prescribed." Plaintiffs allege that the Image Guided Defendants violated this provision by ordering MPA in bulk. This claim fails as a matter of law because Plaintiffs have not alleged—and cannot allege—that Drs. Mathis and O'Brien knew how the MPA used in the procedures was being obtained from Insight. In any event, Plaintiffs have not alleged how they have been harmed by the Image Guided Defendants' alleged ordering in bulk rather than by individual patients. The MPA from NECC would have been the same MPA from NECC regardless of how the details of the prescriptions were handled. Thus, Plaintiffs cannot establish causation as to this alleged negligence.

Virginia Code § 54.1-3410.2 requires that compounding pharmacists comply with the United States Pharmacopeia National Formulary ("USPNF") standards (subsection E) and prohibits such pharmacists from compounding medications that are commercially available (subsection H). But the Introduction of USP-NF 797 states that "The standards in this chapter are intended to apply to all persons who ***prepare*** CSPs [Compounding Sterile Preparations] and all places where CSPs are prepared . . . ." Even more to the point, the document explicitly

[8] Although Plaintiffs rely on the VDCA for their negligence per se arguments, the gravamen of the alleged violations concern fraudulent conduct vis-à-vis misbranded or adulterated products. Accordingly, Plaintiffs need to plead the claims with particularity, which they have not done.

disavows any application to the clinical use of such medications: "The standards in this chapter do not pertain to the clinical administration of CSPs to patients via application, implantation, infusion, inhalation, ***injection***, insertion, instillation, and irrigation, which are the routes of administration." (Relevant portions of USP-NF 797's are attached hereto as **Exhibit 5**.) Because the provisions of §54.1-3410.2 of the Drug Control Act apply only to compounding pharmacies, *not* to interventional radiologists like the Image Guided Defendants, Plaintiffs' claims based on this provision fail as a matter of law.[9]

Virginia Code § 54.1-3457(1) prohibits "[t]he manufacture, sale, delivery, holding, or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded." The allegations in Plaintiffs complaints do not satisfy any of these requirements. Plaintiffs, however, do not allege facts showing that the *Image Guided Defendants* manufactured, sold, delivered, held, or offered for sale the allegedly contaminated MPA. For the most part, they simply allege that Dr. Mathis and Dr. O'Brien administered the contaminated MPA during medical procedures.[10] To the extent that Plaintiffs contend that the medical administration of the steroids constitutes "delivery," this argument fails as a matter of law. To begin with, the other proscribed acts—i.e., manufacturing, selling, holding, and offering for sale—all concern the commercial production and distribution of drugs. Under the principle of *noscitur a sociis*, statutory terms are interpreted in light of adjacent terms. *Cuccinelli v. Rector, Visitors of Univ. of Virginia*, 722 S.E.2d 626, 633 (Va. 2012). Viewed in this light, "delivery" denotes a commercial-type

[9] This is also borne out by the text of the statute. For example, Code § 54.1-3410.2(E) says that "*Pharmacists* shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding." (Emphasis added.) It says nothing about radiologists. Likewise, Code § 54.1-3410.2(H) states that "*Pharmacists* shall not engage in the following . . . ." (Emphasis added). There is no allegation that any of the Image Guided Defendants is a pharmacist. Thus, they could not have violated Code § 54.1-3410.2.

[10] The Plaintiff in *Baker* alleges that Dr. Mathis personally participated in the purchase of the MPA. (Am. Compl. ¶ 21.) But this does not affect the arguments vis-à-vis § 54.1-3457(1).

delivery. It does not mean "delivering" the drug into the body of a patient during a medical procedure.

More to the point, the Drug Control Act defines "administer" to mean "direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner." Va. Code § 54.1-3401. But Code § 54.1-3457(1) does not include "administration" of adulterated products among its proscribed acts. The General Assembly clearly knows how to regulate the "administration" of drugs when it chooses to do so. The fact that Code § 54.1-3457(1) does not include "administration" shows that the General Assembly intended not to include "administration" among its proscribed acts. Accordingly, the allegations of the Complaints do not establish a violation of Code § 54.1-3457(1).

Virginia Code § 54.1-3457(2) prohibits the "adulteration" or "misbranding" of any drug. "Adulteration" is defined at Code § 54.1-3461. "Misbranding" is defined at § 54.1-3461. The Complaints in the present cases do not allege any conduct by the Image Guided Defendants that constitute the adulteration or misbranding of any product. At worst, Plaintiffs allege that the Image Guided Defendants *used* and *administered* adulterated and misbranded products, or made *statements* about them. But the use, administration, and mention of adulterated or misbranded products do not themselves constitute adulteration or misbranding. Accordingly, Plaintiffs fail to allege a violation of Virginia Code § 54.1-3457(2).

The remaining alleged violations of Code § 54.1-3457 require little discussion. **Code § 54.1-3457(3)** forbids the "receipt in commerce" and "delivery . . . thereof for pay or otherwise" of any "misbranded" or "adulterated" drug. As noted above, the Image Guided Defendants did not "deliver" the allegedly contaminated MPA at issue in this case. They

administered it. **Code § 54.1-3457(5)** forbids the **"**dissemination of any false advertisement." But Plaintiffs have not alleged that the Image Guided Defendants disseminated any advertisements, let alone any false ones.[11] Likewise, **Code § 54.1-3457(10)** forbids the "forging, counterfeiting, simulating, or falsely representing . . . any mark, stamp, tag, label, or other identification device authorized or required" by the Virginia Drug Control Act. But the Plaintiffs fail to allege any such falsification of an "identification device" by the Image Guided Defendants. Although Plaintiffs allege that certain invoices misidentified the products that the Image Guided Defendants used, these are not "identification devices" regulated by the Drug Control Act. So this provision does not apply. Finally, **Code § 54.1-3457(12)** prohibits false labeling and advertising concerning a drug's efficacy. But Plaintiffs do not allege that the Image Guided Defendants labeled or advertised the MPA at all—let alone labeled or advertised it regarding the MPA's efficacy.

III. Plaintiffs' gross negligence claims against the Image Guided Defendants fail because the alleged misconduct of the Image Guided Defendants is not the sort of "utter disregard of prudence" that "would shock fair-minded persons."

In the present case, the Plaintiffs represented by Gentry Locke Rakes & Moore[12] assert claims of gross negligence. "Gross negligence, is a degree of negligence showing indifference to another and an utter disregard of prudence that amounts to a complete neglect of the safety of such other person. This requires a degree of negligence that would shock fair-minded persons, although demonstrating something less than willful recklessness." *Cowan v. Hospice Support Care, Inc.*, 603 S.E.2d 916, 918 (Va. 2004). In the present case, the allegations with respect to

[11] The Plaintiffs in *Baker*, *Johnston*, and *Wertz* allege generically that "Defendants" advertised, but make no particular allegations vis-à-vis any of the Image Guided Defendants. In any event, only the Baker case relies on §§ 54.1-3457(5) or -3457(12).

[12] *Artis*, *Bender*, *Bradley*, *Brown (Patricia)*, *Brown (Ronnie)*, *Courtney*, *Epperly*, *Filson*, *Foutz*, *Harris*, *Holbrook*, *Kalinoski*, *McFarlane*, *Shuck*, *Smith (James)*, *Smith (Randolph)*, *White*, *Whitlow*.

the Image Guided defendants fall well short of this mark. The Plaintiffs in these cases acknowledge that Dr. Mathis and Dr. O'Brien were not aware of Insight's decision to purchase MPA from a compounding facility, that the doctors were not aware that the steroids came from NECC, and that they would never have used the steroids if they had known this. Drs. Mathis and O'Brien, in short, are alleged themselves to have been misled by the misconduct of Insight. This is not the sort of "utter disregard of prudence" that "would shock fair-minded persons."

IV. Plaintiffs' battery claims fail because Plaintiffs authorized Dr. Mathis and Dr. O'Brien to inject steroids in their backs.

Certain of the Plaintiffs allege that the Image Guided Defendants committed battery on them inasmuch as Dr. Mathis or Dr. O'Brien failed to disclose that the MPA they used was compounded MPA, rather than commercially available MPA. These claims fail because Plaintiffs have not alleged, and cannot allege, that the Image Guided Defendants performed a *different medical procedure* from the ones that Plaintiffs authorized.

Absent an emergency or unanticipated problem, a physician must obtain a patient's consent prior to treating or operating on the patient; unauthorized treatment constitutes a battery. *Washburn v. Klara*, 561 S.E.2d 682, 685 (Va. 2002). Where, as here, a patient consents to a procedure or treatment, but is not fully informed regarding all aspects of the procedure that may affect a decision to consent, the patient's claim is one for lack of informed consent, which is a negligence claim. *Tashman v. Gibbs*, 263 Va. 65, 556 S.E.2d 772 (2002). It is only where the procedure or treatment exceeds the scope of the patient's consent that a plaintiff has a viable battery claim. *Washburn*, 561 S.E.2d at 685.

In *Tashman*, for example, the plaintiff complained that the defendant physician did not give her all of the information about the risks of surgery and about other types of procedures, but he did inform her about the procedure she was receiving and about some of the risks. 556 S.E.2d at 775. The Court defined this theory as a medical negligence claim requiring expert testimony

on the standard of care related to disclosing information about the procedure and its risks. *Id.* at 777. In *Washburn*, by contrast, the procedure exceeded the scope of the consent. The signed consent form authorized the surgeon to perform a C6-7 diskectomy. But the surgeon performed the procedure at the C-7-T-1 level. Because the surgeon's acts exceeded the patient's consent, the Court held that there was a viable battery claim. 586 S.E.2d at 686.

The allegations in Plaintiffs' complaints resemble those in *Tashman*, not *Washburn*. The procedure in question was image-guided injection of steroids. Unlike *Washburn*, there is no allegation that Plaintiffs did not consent to such treatment. Nor is there any allegation that the Image Guided Defendants performed any procedure other than the image-guided injection of steroids. Plaintiffs simply allege that the Image Guided Defendants failed to alert them of potential hazards created by using compounded MPA—instead of its FDA-approved commercial equivalent—during the procedures. But this is just a case of lack of informed consent like *Tashman*.

It is anticipated that Plaintiffs will argue that the use of compounded steroids, rather than their commercial equivalents, meant that the image guided MPA injection was a different "procedure" from the one the plaintiffs thought they were consenting to. But this has no support in the case law. Every Virginia medical-battery case concerns whether the entire surgical operation was performed without consent, not whether the particular medical supplies used during the operation were used without consent. Indeed, to permit such a claim would require consent for the use of every medical supply and device for every surgery or medical treatment. There is no support in Virginia law for such an onerous requirement. And other jurisdictions have rejected similar claims. *See, e.g.*, *Shannon v. Fusco*, 89 A.3d 1156, 1181 (Md. 2014) (rejecting claim that doctor had a duty to inform patient that FDA had not approved a drug to supplement radiation treatment); *Southard v. Temple University Hosp.*, 781 A.2d 101, 106 (Pa.

2001) (rejecting claim that surgeon had a duty to inform patient of FDA regulatory status of the bone screws used in spinal surgery).

V. Plaintiffs fail to state a claim for fraud.

A. Plaintiffs do not plead their fraud claims with particularity.

Certain of the Plaintiffs have asserted claims of actual fraud against the Image Guided Defendants. These claims fail because they lack the specificity that Rule 9(b) requires. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. . . ." Fed. R. Civ. P. 9(b). To satisfy this requirement, "the pleader usually is expected to specify the who, what, where, and when of the allegedly false or fraudulent representation." *Alternative System Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23 (2004). Thus, for example, a party asserting fraud claims against multiple defendants must, at the very least, state which of them said what. *Ouch v. Federal National Mortgage Ass'n, No.*, 11-12090-RWZ , 2013 WL 139765 (Jan. 10, 2013) (citing *Alternative System Concepts*, 374 F.3d at 29, and *McKenna v. Wells Fargo Bank*, 693 F.3d 207, 218 (1st Cir. 2012)).

In *Ouch*, the plaintiffs brought a putative class action against a variety of mortgage originators, loan services, trustees of mortgage-backed securitization trusts, and law firms. *Id.* at *1. The plaintiffs referred to seven of the defendants collectively as the "originator defendants." In one of their counts, the plaintiffs asserted that these "originator defendants" had engaged in a "fraudulent scheme" to "originat[e] mortgage loans using significantly reduced underwriting standards." *Id.* But the complaint failed to specify "who made what alleged representations when and where to each named plaintiff." *Id.* Accordingly, this Court held that the plaintiffs "fraud claims fail to meet the heightened pleading standard of Rule 9(b)."

The fraud claims asserted by Plaintiffs in the present case are similarly devoid of the detail that Rule 9(b) requires. In certain cases,[13] the Plaintiffs collectively refer to Insight Health Corp. and Image Guided Pain Management (acting through Defendants Dr. Mathis and Dr. O'Brien) as "Insight Imaging – Roanoke." And they assert that "Insight Imaging – Roanoke" represented that they obtained the drug from an FDA-regulated manufacturer. But they fail to specify who among the various Defendants designated as "Insight Imaging – Roanoke" made the actual representations. The fraud claims in these cases also include numerous allegations made "on information and belief." The complaints, however, fail to justify these assertions with any specific facts. Where, as here, a plaintiff fails to state the basis for his belief, allegations made "on information and belief" do not satisfy Rule 9(b)'s particularity requirement. *See United States ex rel. Kavelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 226 n. 8 (1st Cir.2004), abrogated on other grounds as stated in *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 n.7 (1st Cir. 2009).

The other cases asserting fraud are even more devoid of supporting detail. In *Johnston, Baker,* and *Wertz,* the Plaintiffs refer to Image Guided Pain Management, PC, Insight Health Services Corp., Insight Health Corp., Insight Health Services Holdings Corp., and Dr. Mathis and/or Dr. O'Brien collectively as the "Insight Defendants." Their fraud allegations attribute representations to the "Insight Defendants" without specifying which of these defendants made which of these representations, when the representations were made, or what actions the Plaintiffs took in reliance upon the misrepresentations. Moreover, these Plaintiffs allege "on information and belief" that "Image Guided Pain Management, PC learned NECC products manufactured on or after May 2012 could be tainted and contain fungal contamination." (*See*

[13] These are *Artis, Bender, Brown (Patricia), Brown (Ronnie), Courtney, Holbrook, Shuck,* and *White.*

Johnston ¶ 26, *Wertz* ¶ 26.) Not only is this statement an inadequate "information and belief" assertion, see *supra*, it lacks the requisite specificity inasmuch as it fails to state when Image Guided learned of the fungal contamination. Because Plaintiffs' fraud claims lack the specificity that Rule 9(b) requires, this Court should dismiss them.

B. On the alleged facts, plaintiffs cannot show reliance.

Plaintiffs fraud claims fail for the additional reason that, under the facts alleged, they cannot show reliance. To state a claim for fraud, the plaintiff must have relied upon the alleged misrepresentations. *See, e.g.*, *Caperton v. A.T. Massey Coal Co., Inc.*, 740 S.E.2d 1, 9 (Va. 2013). But the only concrete misrepresentations that Plaintiffs allege that the Image Guided Defendants made about the provenance of the MPA used in the procedures are statements made in medical charts, insurance claims, and reports by Dr. Mathis and Dr. O'Brien to plaintiffs' primary care physicians concerning how the procedures went. All of these were statements made after the treatment. So Plaintiffs could not have relied on them in deciding whether to have the steroid injection. Other than boilerplate allegations of reliance, Plaintiffs fail to specify what acts they took in reliance upon the allegedly fraudulent misrepresentations. Because Plaintiffs have not alleged, and cannot allege, any reliance upon the claimed misrepresentations, their fraud claims fail as a matter of law.

VI. Constructive fraud cannot be based on silence because actionable silence must be deliberate.

Certain of the Plaintiffs represented by Gentry Locke have asserted only "constructive fraud" claims against the Image Guided Defendants. These Plaintiffs base their constructive-fraud claims on the Image Guided Defendants' alleged failure to disclose that the MPA that the Image Guided Defendants used during the procedures came from NECC—a compounding pharmacy, not an FDA-regulated drug manufacturer. Yet these same Plaintiffs assert that the Image Guided Defendants did not know from whom Insight Imaging was obtaining the MPA.

Indeed, they allege that Insight Health failed to adequately inform the Image Guided Defendants about the provenance of the MPA.

These Plaintiffs' constructive-fraud-by-omission claims are a legal contradiction in terms. As noted above, Plaintiffs base their claim on a nondisclosure. But silent concealment is actionable as fraud only where the nondisclosure is deliberate. *Hitachi Credit America v. Signet Bank*, 166 F.3d 614, 629 (4th Cir. 1999) (applying Virginia law) (noting that actionable concealment "always involves deliberate nondisclosure designed to prevent another from learning the truth."). Thus, a party cannot base a constructive fraud case on silence where, as here, it alleges that the defendant was unaware of the facts about which it was silent. *Allison v. Shapiro & Burson, LLP*, No. 1:09cv57, 2009 WL 4015410, at *5 (W.D. Va. 2009) ("Virginia law does not recognize a claim for constructive fraud based on an omission because 'a claim for fraud by omission requires deliberate nondisclosure.'") (quoting *Bank of Montreal v. Signet Bank*, 193 F.3d 818, 833 (4th Cir. 1999)); *Rambus, Inc. v Infineon Technologies AG*, 164 F. Supp. 2d 743, 750 (E.D. Va. 2001) *rev'd in part on other grounds* 318 F.3d 1081 (Fed. Cir. 2003) ("Constructive fraud cannot, as a matter of Virginia law, be premised on a fraudulent omission or concealment of a material fact."). In the present case, Plaintiffs base their constructive fraud claims on an omission or concealment of a material fact. Because this is not actionable as constructive fraud, this Court should dismiss these claims.

VII. Plaintiffs' claims under the Virginia Consumer Protection Act fail because they are not stated with particularity and concern manufacturer actions over which the Image Guided Defendants had no control.

Several of the Plaintiffs have asserted claims under the Virginia Consumer Protection Act, Virginia Code § 59.1-196, *et seq.* ("VCPA"). The VCPA prohibits "suppliers" from engaging in specific fraudulent acts or practices in consumer transactions, including misrepresenting goods as those of another; misrepresenting the source, sponsorship, approval or

certification of goods; and misrepresenting that goods are of a particular standard or quality. Va. Code §59.1-200. Plaintiffs' VCPA claims fail for at least three independent reasons.

First, they are not pleaded with particularity. Claims brought under the VCPA are, in essence, fraud claims and so must comply with Rule 9(b)'s heightened pleading requirements. *Nahigian v. Juno Loudoun, LLC*, 684 F. Supp. 2d 731, 741 (E.D. Va. 2010) (holding that "[a]s a claim sounding in fraud, Rule 9(b)'s particularity requirements apply" to VCPA cause of action); *Fravel v. Ford Motor Co.*, 973 F. Supp. 2d 651, 656 (W.D. Va. 2013) (same). For the reasons stated above, Plaintiffs have not pleaded their fraud claims with the requisite particularity. And the additional allegations contained in Plaintiffs' VCPA counts do not add any meaningful detail—they are conclusory and formulaic recitations of the requirements of a VCPA claim. Because Plaintiffs have not pleaded their VCPA claims with particularity, those claims fail as a matter of law.

Second, under the VCPA, a supplier is not liable for an "act or practice of the manufacturer or distributor to the supplier over which the supplier had no control." Va. Code §59.1-207. Thus, the Image Guided Defendants are not liable for the manufacture or compounding of the adulterated MPA by NECC. Moreover, certain complaints concede that the Image Guided Defendants have attested they were unaware of the actual origins of the injected MPA, relying on Insight to provide a safe supply.[14] But to establish a VCPA claim, a plaintiff must demonstrate purposeful deceptive conduct. *See Padin v. Oyster Point Dodge*, 397 F. Supp. 2d 712, 722 (E.D. Va. 2005) ("In order to sustain a claim under the VCPA, a plaintiff must prove that the defendant acted with an intent to deceive or otherwise mislead, i.e. with fraudulent intent . . . ."); *Synergistic International, LLC v. Korman*, 402 F. Supp. 2d 651, 663 (E.D. Va.

[14] *See Bradley, Epperly, Filson, Foutz, Harris, Kalinoski, McFarlane, Smith (James), Smith (Randolph), Whitlow*.

2005) ("To satisfy the [VCPA], a misrepresentation must be 'a false representation,, of material fact, made intentionally and knowingly, with intent to mislead . . . ") (quoting *Richmond Metro. Auth. v. McDevitt St. Bovis, Inc.*, 507 S.E.2d 344 (Va. 1988)). Thus, those complaints fail to state a VCPA claim against the Image Guided Defendants.

Third, the VCPA claims fail as to Dr. Mathis and Dr. O'Brien because they are not suppliers; they are at most *employees* of suppliers. This distinction makes a difference. While a supplier is prohibited from engaging in the enumerated fraudulent acts and can be held liable under the VCPA, the employees and subcontractors of the supplier who execute the transaction are not liable under the VCPA because they are not "suppliers." Va. Code §59.1-200. They did not personally sell Plaintiffs anything. Because liability under the VCPA is limited to acts of "suppliers"—and not their employees or agents—Plaintiffs' VCPA claims against Dr. Mathis and Dr. O'Brien fail as a matter of law.

VIII. The U.C.C. does not apply to the provision of medical services.

Finally, certain of the Plaintiffs assert UCC claims for breach of express and implied warranties. These claims are nonstarters because the UCC does not apply to the sale of medical services. The UCC, as adopted by Virginia, applies only to the sale of goods. Va. Code. § 8.2-102. To state a claim for implied or express warranty under the UCC, a plaintiff must show that the transaction in question was a sale of goods (rather than, say, services). *See* Va. Code §§ 8.2-313–15 (setting forth the requirements for establishing express and implied warranties). *See also Coakley v. Williams*, 706 F.2d 456, 459 (4th Cir. 1983) ("Whether the U.C.C. applies turns on a question as to whether the contract . . . involved principally a sale of goods, on the one hand, or a provision of services, on the other."). "Thus, before applying the U.C.C., courts generally examine the transaction to determine whether the sale of goods predominates." *Princess Cruises, Inc. v. General Elec. Co.*, 143 F.3d 828, 832 (4th Cir. 1998).

Under Virginia law, the provision of health care by health care professionals constitutes the sale of services even where, as here, part of the transaction involves the transfer of drugs or medical devices. *Gressman v. Peoples Service Drug Stores, Inc.*, 10 Va. Cir. 397 (Richmond Cir. Ct. Feb. 9, 1988) (claim against pharmacist for wrongly filling prescription was sale of services that did not fall under the UCC); *Coffman v. Arthrex, Inc.*, 69 Va. Cir. 17 (August Co. Cir. Ct. March 31, 2005) (surgical installation of faulty biodegradable screw was the provision of services, not goods). *Cf. Commonwealth of Virginia Dept. of Taxation v. Bluefield Sanitarium, Inc.*, 216 Va. 686, 222 S.E.2d 526 (1976) (holding, in tax case, that a hospital was not a retailer of drugs because it acquired them for use in caring for patients). This is consistent with the law of other jurisdictions. *See Royer v. Catholic Medical Center*, 741 A.2d 74 (N.H. 1999) (collecting cases and stating that "[a] majority of the jurisdictions" that have addressed the issue have dismissed products liability claims against health care providers, "similarly reasoning that the health care provider primarily renders a service, and that the provision of a prosthetic device is merely incidental to that service.").

The transactions in the present case did not concern the sale of goods. They concerned the provision of medical services—i.e., radiological imaging and the concomitant administration of steroids. Although the patients paid for the steroids used in that procedure, that sale was incidental to the health care services that the Image Guided Defendants provided. Because the transactions predominately involved the provision of medical services, not the sale of goods, the UCC does not apply and Plaintiffs' UCC claims fail as a matter of law.

CONCLUSION

For all of the foregoing reasons, the Image Guided Defendants respectfully request that this Court dismiss all of the claims against them other than ordinary negligence.

IMAGE GUIDED PAIN MANAGEMENT, P.C., JOHN M. MATHIS, M.D., and ROBERT F. O'BRIEN, M.D.

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CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing dated August 27, 2014.

/s/ John T. Jessee
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